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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/835,995	04/17/2001	Charlotte Soderberg	00146regUS	8766

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COZEN O ' CONNOR, P.C.
1900 MARKET STREET
PHILADELPHIA, PA 19103-3508

EXAMINER	
LANDSMAN, ROBERT S	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 01/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/835,995	Applicant(s) SODERBERG ET AL.	
	Examiner Robert Landsman	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 October 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29,31 and 35-82* is/are pending in the application.

4a) Of the above claim(s) *1-29 and 36-79* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *31,35 and 80-82* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Formal Matters

A. The Amendment filed 10/28/03 has been entered into the record.

B. Claims 1-29, 31 and 35-82 are pending in the application. Claims 1-29 and 36-79 have been withdrawn as being drawn to a non-elected invention. Therefore, claims 31, 35 and 80-82 are the subject of this Office Action.

C. All Statutes under 35 USC not found in this Office Action can be found, cited in full, in a previous Office Action.

2. Claim Rejections - 35 USC § 101

A. Claims 31, 35 and 80-82 remain rejected for the reasons already of record on pages 2-3 of the Office Action dated 7/29/03. Applicants argue that the claimed polypcptide can be used for the production of antibodies; to make hybridization probes and primers to dctcct nucleic acid molecules that encode the claimed polypeptide, and to localize gene cxpression in tissue samples; to produce a variant or chimeric polypeptide; to create transgenic mammals; to dctcct pharmacogcnomically-relevant polymorphisms in individuals; to search for drugs as ligands or antagonists of the claimed polypeptide; and for gene therapy. They argue that another use of the claimcd polypeptide is the identification of tissue source based on expression of the GPCR. Thus, it is clear that the claimed invention has real-world, practical uses. Applicants argue that assay methods have an immediately realizable real-world use. Genes encoding GPCRS can be used, for example, even in cases where littlc is known as to how a particular GPCR works. No additional experimentation would be required, therefore, to determine whether a GPCR has a practical use as all GPCRs havc at least one practical use, and the skilled artisan would not question this. Applicants further argue that they have demonstratcd a "substantial likelihood" of utility of the present invention and that the situation for GPCRs is distinct from that of Brenner. Finally, Applicants argue that issued US Patents relating to GPCRs, including those without a confirmed ligand, are evidence of an art recognized utility for GPCRS whose natural function or association with a disease state is unproven and that, as acknowledged by the Examiner, all U.S. Patents arc presumcd valid. Accordingly, Applicants assume that applications presenting similar proofs of utility under 101 should, like the issued patents, also satisfy 35 USC 101.

These arguments have been considered, but are not deemed persuasive. While it may be true that the protein of the present invention, or its encoding polynucleotide, may have uses as argued above, the fact remains that these uses are neither specific, nor substantial. In other words, basically any protein or polynucleotide can be used for the production of antibodies, to make hybridization probes and primers to detect nucleic acid molecules that encode the claimed polypeptide, and to localize gene expression in tissue samples, to produce a variant or chimeric polypeptide, to create transgenic mammals, to detect pharmacogenomically-relevant polymorphisms in individuals, to search for drugs as ligands or antagonists of the claimed polypeptide, for gene therapy, etc. These uses are not specific for the molecules of the present invention. Not knowing the natural ligand or associated disease state will not allow the artisan to identify the specific or substantial utility of the claimed invention. Without knowing the function or any associated disease states of the protein or its encoding polynucleotide, then the production of antibodies, the identification of ligands, tissue localization, etc. will also not be useful. In other words, if the function of the protein is not known, then it is not understood how the artisan would utilize the antibodies, ligands, etc. To use these without a specific knowledge of the protein of the present invention would be to use these as a tool for further research and as argued previously, a patent is not a hunting license. Respectfully, Applicants are saying "we identified a protein with no known function and we want to prohibit others from studying it until we can characterize it." Simply knowing that the protein of the present invention is a GPCR is not sufficient since GPCRs constitute a superfamily of proteins, which have a wide range of functions from, for example, pain relief, to vasoconstriction, to memory. Applicants cannot simply assert a utility of a GPCR without further characterization. Applicants also state that, according to the Examiner, all U.S. Patents are presumed valid and, accordingly, Applicants assume that applications presenting similar proofs of utility under 101 should, like the issued patents, also satisfy 35 USC 101. Again, the Examiner states that all US Patents are presumed valid and have satisfied the requirements for patentability under 35 USC 101.

3. Claim Rejections - 35 USC § 112, first paragraph - enablement

A. Claims 31, 35 and 80-82 remain rejected under 35 USC 112 for the reasons already of record on page 3 of the Office Action dated 7/29/03 as well as for the reasons given in the above rejection under 35 USC 101. Applicants argue that the claimed invention is enabled because it has utility as argued previously. Applicants' arguments have been fully considered, but are not found to be persuasive for the reasons discussed above.

B. Claims 80-82 remain rejected under 35 USC 112, first paragraph, for the reasons already of record on pages 3-4 of the Office Action dated 7/29/03. Applicants argue that the claims, as amended, recite "homologs of SEQ ID NO:2 having at least 95% sequence homology." However, these claims do not recite a functional limitation. Proteins which are at least 95% identical" to the protein of SEQ ID NO:2 would encode for a protein with one or more amino acid substitutions, deletions, insertions and/or additions to the protein of SEQ ID NO:2. Applicants provide no guidance or working examples of proteins which are at least 95% identical to SEQ ID NO:2, nor have they provided any guidance as to what critical residues are required to maintain the functional characteristics of the protein of SEQ ID NO:2. Furthermore, it is not predictable to one of ordinary skill in the art how to make a functional sodium channel protein which is less than 100% identical to that of SEQ ID NO:2.

In summary, the breadth of the claims is excessive with regard to Applicants claiming all proteins which are at least 95% identical to SEQ ID NO:2. There is also a lack of guidance and working examples of these proteins as well as which residues are critical for protein function. These factors, along with the lack of predictability to one of ordinary skill in the art as to how to make a functional protein other that that of SEQ ID NO:2 leads the Examiner to maintain that undue experimentation is necessary to practice the invention as claimed.

4. Claim Rejections - 35 USC § 112, first paragraph – written description

A. The rejection of claims 80-82 under 35 USC 112, first paragraph, has been withdrawn in view of Applicants' amendment to the claims to recite "homologs of SEQ ID NO:2 having at least 95% sequence homology" and that one skilled in the art would recognize that Applicants were in possession of the claimed invention.

5. Claim Rejections - 35 USC § 112, second paragraph

A. All rejections under 35 USC 112, second paragraph, have been withdrawn in view of Applicants' cancellation of the rejected claims.

6. Claim Rejections - 35 USC § 102

A. The rejection of claim 35 under 35 USC 102 as being anticipated by Bonaldo et al. has been withdrawn in view of Applicants cancellation of the independent claim rejected by Bonaldo regarding a fragment of at least 5 amino acids of SEQ ID NO:2.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (703) 306-3407. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Fax draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert Landsman, Ph.D.
Patent Examiner
Group 1600
December 24, 2003

Gary L. Kunz
GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600